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EXAMINER
STANTON, B

ART UNIT: 1804 | PAPER NUMBER: 5

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DATE MAILED: 08/07/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

For Restriction Purposes Only

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made fina

A shortened statutory period for response to this action is set to expire 6 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-94
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-36 are pending in the applicatic

Of the above, claims _____ are withdrawn from consideratior

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-36 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-946).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been receiv ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 1-36 are pending in the instant Application.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 30, 31, 33, and 34 drawn to embryonic stem cell compositions, classified in Class 435, subclass 240.21.

II. Claims 8, 9, 11, and 12, drawn to primordial germ cell compositions, classified in Class 435, subclass 240.21.

III. Claim 10, drawn to embryonic ectoderm cell compositions, classified in Class 435, subclass 240.21.

IV. Claims 13, 14 and 29, drawn to growth factor compositions, classified in Class 530, subclass 350.

V. Claims 15-19 and 25-28, drawn to methods of making embryonic stem cells from primordial germ cells, classified in Class 435, subclass 240.21.

VI. Claims 20-24, drawn to methods of making embryonic stem cells from embryonic ectoderm cells, classified in Class 435, subclass 240.21.

VII. Claim 32, 35, and 36, drawn to methods of screening growth factor compositions, classified in Class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-III are distinct, each from the other, because they are drawn to materially different cellular compositions each requiring separate areas of search and consideration in the non-patent literature. Each of the three inventions are drawn different cell types that are morphologically and phenotypically distinct and examination of each such cell must take into account the separate properties of the several cells.

The inventions of the any of groups I-III and the invention of group IV are distinct from one another because they are drawn to distinct compositions that requrie separate areas of search and consideration. The inventions of groups I-III are drawn to multicomponent cellular compositions whereas the invention of group IV is drawn to proteinacious growth factor compositions which require divergent areas of search and consideration directed towards the nature of the claimed composition. Further, the compositions of the invention of group IV may be used to grow any cells and the cellular compositions do not require the growth factors *per se* to support patentability.

The cells of the invention of group I are distinct from any of the methods of groups V-VII because the claimed cells are not utilized in any of said methods and therefore the search and

consideration of said methods do not require analysis of the claimed cells *per se*. Similarly, the inventions of group II is distinct the methods of groups VI, because the cells of the invention of group II are not used in any of said methods. Further, the invention of group III is distinct from the methods of group V because the cells of the invention are not used in said methods.

Inventions V and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the product (embryonic stem cells) may be prepared using inner cell mass cells. Similarly, inventions VI and III are related as process of making and product made and said product may also be made starting with inner cell mass cells.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the cells of the invention of group II may be used in materially different fashion as evidenced by its use in either of the methods of groups V or VII. Similarly, the inventions of groups III and VII are related as product and process of use and the cells of the invention of group III may be used in materially different fashions as evidenced by their use in either of the methods of groups VI or VII.

Inventions IV and any of the inventions of groups V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the compositions of the invention of group II may be used in materialy different manners as evidenced by thier use in the separate methods of the inventions of groups V-VII.

The inventions of groups V and VI are distinct, one from the other, because they utilize distinct starting materials and analysis of said starting materials requires distinct areas of search in the non-patent literature.

The inventions of either of the inventions of groups V and VI are each distinct from the invention of group VII because the latter methods are drawn to materially different processes wherein undefined growth factors are analyzed and such analysis requires divergent areas of search from those required for consideration of the defined systems of the inventions of groups V or VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, recognized divergent subject matter and further because the searches required for the different inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Mr. David Perryman on 10/31/94 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton whose telephone number is (703) 308-2801. The examiner can normally be reached Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached at (703) 308-3153. The fax phone number for this Group is (703) 308-4312.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Brian R. Stanton, Ph.D.
02 August 1995

Jasemine C. Chambers

JASEMINE C. CHAMBERS
PRIMARY EXAMINER
GROUP 1800